

09/133,119


**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/133,119	08/12/98	LE	J NYU93-01M4AZ
HAMILTON BROOK SMITH & REYNOLDS 2 MILITIA DRIVE LEXINGTON MA 02173			EXAMINER
HM12/0922			ART UNIT PAPER NUMBER
			1642

DATE MAILED:

09/22/99

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS
OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 4, 6, 12, 14 is/are allowed.
- ☒ Claim(s) ~~1-3, 5, 7-11, 13, 15-17~~ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Claims 1-17 are pending.

2. Claims 1-3, 5, 7-11, 13, 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "selectively hybridizes" in claims 1 and 2 and the recitations "specifically hybridize" in claims 7 and 8 are vague and indefinite. The type of DNA hybridization that qualifies as selective or specific is unclear.

Absent the recitation of specific stringency conditions, the metes and bounds of the recitation "hybridizes" in claims 1-2, 7-8 and the recitation "hybridizes under conditions of moderate stringency" in claim 3 are unclear.

The recitation "derivative" in claims 5 and 17 is vague and indefinite. The nature of molecule or modification that qualifies as "derivative" is unclear.

3. Claims 2-3, 5, 10-11, 13, 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims 2-3, 5, 10-11, 13 and 17 are broadly drawn to single polypeptides encoded by either SEQ ID NO:2 or SEQ ID NO:4, each polypeptide independently binding to TNF α . However, SEQ ID NO:2 and SEQ ID NO:4 encode, separately, the variable region of the heavy and light chains of an antibody with TNF specificity. It is well known in the art of immunology that both the heavy and light chains of an antibody together contribute to the antigen binding specificity of the intact antibody. Polypeptides comprising just the light chain variable region or just the heavy chain variable region rarely bind to antigen. Thus, one of skill in the art could not make and use the broadly claimed antibody with a reasonable expectation of success.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 7, 8 are rejected under 35 U.S.C. 102(b) as being anticipated either by p. 167 of the 1994-1995 Promega Catalog or p.962 of Lehninger's Biochemistry Textbook (1975). Page 167 of the Promega Catalog discloses nucleic acid molecules (bulk dNTPs) which would hybridize to SEQ ID NO:2 or SEQ ID NO:4 and are the same as that claimed in claims 1, 7© and 8(c). Figure 34-1 of Lehninger's Biochemistry Textbook also discloses nucleic acid molecules that would hybridize to SEQ ID NO:2 or SEQ ID NO:4 and are the same as that claimed in claims 1, 7© and 8(c).


6. Claims 9, 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by pages 152-153 of the 1993-1994 New England Biolabs Catalog. Pages 152-153 disclose an expression vector comprising the single basepair sequences or triplet codons, that qualify as "the nucleic acid molecule of claims 1, 7 and 8," and thus, are the same as that claimed.

7. Claims 1, 7, 8, 9, 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Accession number M32046 (15 June 1990) or N90300 (1 Nov. 1989). Both Accession No. Disclose a nucleic acid molecule that would hybridize to either SEQ ID NO:2 of SEQ ID NO:4 and expression vectors comprising said nucleic acid molecules, that are the same as that claimed.

8. Claims 1-6, 9-17 are free of the art.

9. Claims 4, 6, 12, 14 are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nancy A Johnson
Primary Examiner

Nancy A. Johnson, Ph.D.

Patent Examiner, Group 1642

September 18, 1999

FORM PTO - 892 MISSING FROM
THE FILE